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10/803,080	03/18/2004	Richard L. Cunningham	IMMR-IMD0194 (034701-111)	4170

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EXAMINER	
SIM, YONG H	

ART UNIT	PAPER NUMBER
2629	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.**	**Applicant(s)**	
	10/803,080	CUNNINGHAM ET AL.	
	Examiner	**Art Unit**	
	YONG SIM	2629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,25-28 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-20,25-27 and 30-33* is/are rejected.

7)☒ Claim(s) *5 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

TAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

At the outset, the Applicants are thanked for the thorough review and consideration of the Office Action dated 1/25/2008.

With respect to the Applicant's argument regarding claim 2, the Applicants argue that there is no apparent reason why one skilled in the art would have the motivation to use the beads in Madsen for haptic effect purposes.

However, Examiner respectfully disagrees. Anderson teaches a device comprising an interface member for simulating a human body part including a mechanism which can selectively be controlled to simulate the density variance by applying a compressive force, but Anderson fails to teach such human body part comprised of said beads in claim 2. As previously described in the rejection of claim 2, Madsen was introduced to overcome the simple deficiency of having beads as a component for a simulated human body part. It would have been obvious to a person having ordinary skill in the art to incorporate the idea of using a simulated human body part comprised of beads into the simulated human body part of Anderson to give a more exhaustive structure to the simulated bone for a realistic surgery simulation.

Further, the Applicant alleges that combining Madsen's beads with Anderson's force-feedback wheel assembly would render Anderson's assembly inoperable for it intended purpose, because beads could get caught between the force wheel and the needle.

However, Examiner respectfully disagrees since the simulated human body part including beads would replace one of the body parts such as a spinal column which can be one of the selected sites on the manikin (See Anderson: Para 0175) in Anderson, thereby allowing the wheels to press on the spinal column as a whole to create a variance of density instead of pressing on the individual beads.

Therefore, the argument is moot.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1 – 4, 6, 8 – 16, 18 – 20, 25 – 27, 30 – 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen et al. (Hereinafter "Madsen" US 6,318,146 B1) in view of Anderson et al. (Hereinafter "Anderson" US 2004/0009459 A1).**

Re claim 1, Madsen teaches medical phantom body part material comprising beads suitable for various parts of human body (Madsen: Col. 5, lines 1 - 16).

But does not teaches comprising: an interface member including; a manipulandum movable in a degree of freedom, the manipulandum configured to penetrate the material; a sensor configured to output a position signal based on the position of the manipulandum; and an actuator configured to change the density of the material within at least a portion of the interface member in response to the position signal, wherein the change in density of the material imparts a haptic effect to the manipulandum.

However, Anderson teaches a device, comprising: an interface member ("Manikin" Fig. 13) including; a manipulandum ("Needle" Fig. 13) movable in a degree of freedom (See Fig. 13, the needle is movable in x, y and z axis.), the manipulandum configured to penetrate a manikin (See fig. 13); a sensor configured to output a position signal based on the position of the manipulandum (Para 0165; "the position of the needle is detected through an encoder and the positioning sensor"); and an actuator configured to change the simulated density of a material in response to the position

signal, wherein the change in the simulation of the density imparts a haptic effect to the manipulandum (Para 0166; “forces are encoded and transferred to the servo motor that controls the friction resistance between the force wheel and the needle.").

Therefore, taking the combined teachings of Madsen and Anderson, as a whole, it would have been obvious to a person having ordinary skill in the art to incorporate the idea of having the manipulandum with an actuator which can selectively be controlled to simulate the density variance by applying a compressive force as taught by Anderson into the phantom/simulated body part material comprising beads of Madsen to obtain a manipulandum comprising an actuator configured to selectively change/vary the density of a material comprising beads in response to the position signal to give the user more realistic and accurate experience for a surgery simulation.

Re claim 2, the combined teachings of Madsen and Anderson teach the device of claim 1, wherein the material includes a plurality of compressible beads (Madsen: Col. 5, lines 1 - 16).

Re claim 3, the combined teachings of Madsen and Anderson teach the device of claim 1, wherein the material includes a plurality of compressible beads (Madsen: Col. 5, lines 1 - 16).

But does not expressly teach polystyrene beads.

However, Examiner acknowledges that specifying the type of material for the beads is not a required design feature, but is one feature out of many alternative design features, it is an obvious matter of design choice to have polystyrene beads.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use polystyrene beads to give the simulation model added flexibility and durability.

Re claim 4, Anderson teaches wherein the interface member includes a simulated bone structure (Para 0174; “performs a simulated vertebroplasty on the simulated bony structure.”).

Re claim 6, Anderson teaches wherein the actuator is a clamp coupled to the interface member (See fig. 14. The baffle is a clamp which clamps the needle between the wheels.).

Re claim 8, Anderson teaches the actuator being a first actuator, the device further comprising a plurality of actuators including the first actuator, each actuator from the plurality of actuators being an individually actuatable clamp (Para 0174; “a selected site surface on the manikin which comprises various insertion site locations along the back of the manikin over the spinal region.” The manikin comprises various insertion locations with various actuators which are clamps as can be seen in Fig. 13).

Re claim 9, Madsen teaches medical phantom body part material comprising beads suitable for various parts of human body (Madsen: Col. 5, lines 1 - 16).

But does not teach a device comprising: a manipulandum movable in a degree of freedom; a sensor configured to output a position signal based on a position of the manipulandum; a retainer defining an interior in which a material is disposed, the material configured to receive an object moved by the manipulandum and having a selectively variable density; and an actuator coupled to the retainer, the actuator configured to output haptic feedback via the retainer based on the position signal.

However, Anderson teaches a device, comprising: a manipulandum ("The structure that the Needle is attached to" Fig. 13 or the robotic arm in Fig. 12) movable in a degree of freedom (See Fig. 13, the needle is movable in x, y and z axis.); a sensor configured to output a position signal based on a position of the manipulandum (Para 0165; "the position of the needle is detected through an encoder and the positioning sensor"); a retainer ("Manikin" Fig. 13) defining an interior in which a material is disposed (See fig. 13), the retainer configured to receive an object moved by the manipulandum; and an actuator coupled to the retainer (See fig. 13), the actuator configured to change the simulated density of a material in response to the position signal, wherein the change in the simulation of the density imparts a haptic effect to the manipulandum. (Para 0166; "forces are encoded and transferred to the servo motor that controls the friction resistance between the force wheel and the needle.").

Therefore, taking the combined teachings of Madsen and Anderson, as a whole, it would have been obvious to a person having ordinary skill in the art to incorporate the idea of having a device comprising a retainer and an actuator coupled to the retainer wherein the actuator can selectively be controlled to simulate the density variance by applying a compressive force as taught by Anderson into the phantom/simulated body part material comprising beads of Madsen to obtain a device comprising a manipulandum and a retainer wherein the simulated body material is disposed within the retainer and further comprising an actuator configured to selectively change/vary the density of a simulated body material comprising beads in response to the position signal to give the user more realistic and accurate experience for a surgery simulation.

Re claim 10, Anderson teaches wherein the manipulandum includes a first portion (Frame, Fig. 13) and a second portion (Sheathe, Fig. 13), the second portion configured to be removably coupled to the object (“Needle” Fig. 13).

Re claim 11, Anderson teaches wherein the manipulandum is configured to move in a rotary degree of freedom about an axis, and move simultaneously along the axis (See Para 0164. The robotic arm with six degrees of freedom is controlled by a user's manipulation which can rotate and move simultaneously along an axis.).

Re claim 12, the combined teachings of Madsen and Anderson teach the device of claim 9.

But does not expressly recite a simulated pedicle of a vertebrae.

However, as Examiner acknowledges that it is well known in the art that vertebroplasty procedure as described by Anderson is performed for the treatment of disease involving pedicle of a vertebrae.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a simulated pedicle of a vertebrae for performing a simulated vertebroplasty procedure in order to achieve more realistic hand-eye coordination.

The limitations of claim 13 are substantially similar to the limitations of claim 4. Therefore, it has been analyzed and rejected substantially similar to claim 4.

Re claim 14, Anderson teaches wherein the retainer is configured to compress the material in response to actuation of the actuator (See Fig. 13. The baffle and the material in response to the actuation of the servo motor.).

Re claim 15, Anderson teaches wherein the retainer is configured to modify a density of the material based on the position signal (Para 0166; “forces are encoded and transferred to the servo motor that controls the friction resistance between the force wheel and the needle. The resistance forces are calculated from the physical properties/different densities of the tissue around the needle").

Re claim 16, Anderson teaches wherein the retainer is a clamp having an opening, the actuator including a motor configured to modify a size of the opening based on the position signal (See Fig. 13, when the servo motor activates to turn the servo wheel, the baffle compresses the wheels to change the size of the opening for the needle.).

Re claim 18, Anderson teaches further comprising: a guide (“Sheathe” Fig. 13) configured to receive at least a portion (“Needle” Fig. 13) of the manipulandum, the guide being removably coupled adjacent to the retainer (See fig. 13).

Re claim 19, Anderson teaches wherein the manipulandum is movable in two degrees of freedom (Para 0156; “Each end of the curved frame is placed in a channel of a support which it can slide along in and rotate.”)

Re claim 20, Anderson teaches wherein the manipulandum is movable in a rotary degree of freedom and a linear degree of freedom (Para 0156; “Each end of the curved frame is placed in a channel of a support which it can slide along in and rotate.”).

The limitations of claim 25 are substantially similar to the limitations of claim 4. Therefore, it has been analyzed and rejected substantially similar to claim 4.

The limitations of claim 26 are substantially similar to the limitations of claim 2. Therefore, it has been analyzed and rejected substantially similar to claim 2.

The limitations of claim 27 are substantially similar to the limitations of claim 3. Therefore, it has been analyzed and rejected substantially similar to claim 3.

Re claim 30, Madsen teaches medical phantom body part material comprising beads suitable for various parts of human body (Madsen: Col. 5, lines 1 - 16).

But does not teaches a method, comprising: receiving a position signal via a sensor, the position signal associated with a position of a manipulandum, at least a portion of the manipulandum penetrating a material within an interface member, the material having a selectively variable density; and adjusting the density of the material within at least a portion of the interface member via an actuator coupled to the sensor, wherein the adjusting of the density imparts a haptic effect onto the manipulandum.

However, Anderson teaches a method, comprising: receiving a position signal via a sensor, the position signal associated with a position of a manipulandum (Para 0165; “the position of the needle is detected through an encoder and the positioning sensor”), at least a portion of the manipulandum penetrating an interface member (“manikin” Fig. 13);and an actuator configured to change the simulated density of a material in response to the position signal, wherein the change in the simulation of the density imparts a haptic effect to the manipulandum (Para 0166 “FIG. 14, shows an enlarged view of the needle portion of the device and its interaction with encoders of the interface

which allow the position of the needle to be continuously tracked. A force wheel in proximity to the needle implements haptic feedback in response to signals received by a system processor.").

Therefore, taking the combined teachings of Madsen and Anderson, as a whole, it would have been obvious to a person having ordinary skill in the art to incorporate the idea of having a device comprising an interface and an actuator coupled to the interface wherein the actuator can selectively be controlled to simulate the density variance by applying a compressive force as taught by Anderson into the phantom/simulated body part material comprising beads of Madsen to obtain a device comprising a manipulandum and an interface wherein the simulated body material is disposed within the retainer and further comprising an actuator configured to selectively change/vary the density of a simulated body material comprising beads in response to the position signal when the manipulandum penetrates the material disposed within the manikin to give the user more realistic and accurate experience for a surgery simulation.

Re claim 31, Anderson teaches wherein the varying the density includes applying a compressive force to the interface material via an actuator (See Fig. 13, when the servo motor activates to turn the servo wheel, the baffle compresses the wheels to change the size of the opening for the needle.).

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Re claim 33, Madsen teaches medical phantom body part material comprising beads suitable for various parts of human body (Madsen: Col. 5, lines 1 - 16).

But does not teach an interface member for use with a haptic feedback device including a manipulandum movable in a degree of freedom, the interface member configured to be penetrated by the manipulandum, the interface member comprising:

a material portion configured to be penetrated by at least a portion of a manipulandum, the material portion having a selectively variable density;

a sensor configured to measure a position of the manipulandum within the material portion and output a position signal associated with the measured position; and

an actuator coupled to the retainer, the actuator configured to change the density of the material portion in response to the position signal, wherein the change in density of the material imparts a haptic effect onto the manipulandum.

However, Anderson teaches a device, comprising: an interface member ("Manikin" Fig. 13) for use with a haptic feedback device (See Fig. 13) including a manipulandum ("The structure that the Needle is attached to" Fig. 13 or the robotic arm in Fig. 12) movable in a degree of freedom (See Fig. 13, the needle is movable in x, y and z axis.); an interface ("Manikin" Fig. 13) configured to be penetrated by at least a portion of a manipulandom (See fig. 13)a sensor configured to output a position signal based on a position of the manipulandum (Para 0165; "the position of the needle is detected through an encoder and the positioning sensor"); the actuator configured to change the simulated density of a material in response to the position signal, wherein the change in the simulation of the density imparts a haptic effect to the manipulandum. (Para 0166; "forces are encoded and transferred to the servo motor that controls the friction resistance between the force wheel and the needle.").

Therefore, taking the combined teachings of Madsen and Anderson, as a whole, it would have been obvious to a person having ordinary skill in the art to incorporate the idea of having a device comprising a retainer and an actuator coupled to the interface wherein the actuator can selectively be controlled to simulate the density variance by applying a compressive force as taught by Anderson into the phantom/simulated body part material comprising beads of Madsen to obtain a device comprising a manipulandum and a manikin/interface wherein the simulated body material is disposed within the manikin/interface and further comprising an actuator configured to selectively change/vary the density of a simulated body material comprising beads in response to the position signal when the manipulandum penetrates the material disposed within the manikin to give the user more realistic and accurate experience for a surgery simulation.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 7 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen in view of Anderson, as applied to claims 1 – 4, 6, 8 – 16, 18 – 20, 25 – 27, 30 – 31 and 33 above, and further in view of van Oostrom et al. (Hereinafter "Oostrom" US 6,921,267 B2).**

Re claim 7, the combined teachings of Madsen and Anderson teaches the device of claim 1, wherein the actuator is an air controlled actuator (Anderson: See fig. 16)

But does not expressly teach wherein the actuator is a vacuum coupled to the interface member.

However, Oostrom teaches a simulated lung for use in a real time simulated medical procedure comprising a vacuum pressure source and a positive pressure source.

Therefore, taking the combined teachings of Madsen, Anderson and Oostrom, as a whole, it would have been obvious to a person having ordinary skill in the art to incorporate the idea of using the vacuum source to control the pressure of a simulated body part as taught by Oostrom into the device comprising an actuator which is air controlled as taught by Madsen and Anderson to obtain a device comprising an air controlled actuator for the surgery simulation wherein a vacuum source is used to accurate simulate the density changes of the simulation model.

The limitations of claim 32 are substantially similar to the limitations of claim 7. Therefore, it has been analyzed and rejected substantially similar to claim 7.

7. **Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen in view of Anderson, as applied to claims 1 – 4, 6, 8 – 16, 18 – 20, 25 – 27, 30 – 31 and 33 and above, and further in view of Delp et al. (Hereinafter "Delp" US 5,682,886).**

Re claim 17, the combined teachings of Madsen and Anderson teach the device of claim 9.

But does not expressly teach wherein the manipulandum is a screwdriver and the object is a screw.

However, Delp teaches a computer-assisted surgical system wherein a simulation jig is provided comprising a screw and a screwdriver to insert into bones (Delp: Col. 19, lines 53 - 60).

Therefore, taking the combined teachings of Madsen, Anderson and Delp, as a whole, it would have been obvious to a person having ordinary skill in the art to incorporate the idea of using a screw and a screw driver for a surgery simulation as taught by Delp into the device of Madsen and Anderson to obtain a device comprising a manipulandum wherein the manipulandum comprises a screwdriver and a screw to simulate a bone surgery while providing haptic feedback to give the operator more realistic feel for the surgery simulation.

Allowable Subject Matter

8. Claims 5 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YONG SIM whose telephone number is (571)270-1189. The examiner can normally be reached on Monday - Friday (Alternate Fridays off) 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amr Awad can be reached on (571) 272-7764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YONG SIM/
Examiner, Art Unit 2629

/AMR AWAD/
Supervisory Patent Examiner, Art Unit 2629

8/3/2008